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Characterisation of Sustained Release Bilayer Tablets of Pioglitazone and Metformin

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Short Commentary

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ABSTRACT

Hypoglycemia is a term used to represent high amount of sugar in blood. It occurs due to lack of insulin in the body, which regulates glucose level regularly. The term Diabetes is used as a metabolic disorder which indicates high levels of glucose in the blood.

Sustained release Bilayered tablets are one of the novel techniques which show better results than the conventional tablets.

Short Commentary

Drug delivery system is a term used to deliver the drug to the desired part of the body or to release the drug at the site of action. There are different types of drug delivery systems which includes Controlled release drug delivery systems, Transdermal drug delivery systems, ophthalmic drug delivery systems. This drug delivery system is one of the technique used for the treatment of Diabetes [1-3]. This Bilayer tablets is one of the novel technique which is advanced than the conventional tablets are used as the agents for the drug delivery [4].

Bilayered tablet or Dual release tablet is a unit compressed tablet dosage form intended for oral application. It contains two layers in which one layer having conventional or immediate release part of single or multiple actives; another layer is sustained or controlled release part of single or multiple types [5]. They are also called as Bilayer tablet, multi-layer matrix tablet.

A bilayer tablet is a type of multiple compressed tablets. Tablets are composed of two layers of granulation compressed together. Monograms and other distinctive marking may be compressed in the surface of the bilayer tablets [6]. Coloring the separate layer provide many possibilities for unique tablets identity.

Advantages of Bilayered Tablets

1. Bilayer tablets are mainly used in treatment of type 2 Diabetes [7].
2. Bilayer tablets are used to deliver loading and Maintaining doses separately and continuously for a long period of time.
3. Bilayer tablets are used as floating tablets, in which one layer will be floating for a small period of time until the drug totally released.
4. Bilayer tablets are used to deliver the two different drugs in different profiles.

In this Bilayered Tablets Pioglitazone hydrochloride [8-10] is used as immediate release layer. Pioglitazone is a drug belongs to Thiazolidinedione class which is used to control high blood glucose in patients of Type 2 Diabetes. Metformin hydrochloride is a drug belongs to class of Biguanides which is used to restore the body response to insulin and helps in improving the sensitivity to insulin.

The half-life of Pioglitazone hydrochloride is 3 hrs Initially, Pioglitazone hydrochloride was released as an immediate release layer by using Cross Carmellose sodium as an Super disintegrant which releases the loading dose and then maintenance dose of Metformin will be released continuously for a time period of 10-12 hours [11].

The half-life of Metformin Hydrochloride is 5-6 hrs, hence it is a suitable candidate for the design of controlled or sustained release drug delivery system.

The release of metformin was sustained by using the natural gum extracts like Xanthan gum, Guar gum. This allows the drug release sustained and continuous for a long period of time.

The evaluation of Bilayered tablets of Metformin and Pioglitazone helps in releasing the drug to the site of action by acting as Maintenance dose and the loading dose.

Pre-formulation study was done initially and results were directed the further course of formulation [12].

Pioglitazone Hydrochloride granules were compressed by using Direct compression and Metformin HCl granules were mixed with different compositions of natural gums by using Wet granulation.

Granules were evaluated for Physico-chemical tests such as bulk density, tapped density, Loss on Drying (LOD) and compressibility index before being punched as tablets. Tablets were tested for weight variation, thickness, hardness and friability as per IP procedure.

Dissolution profile was compared with Pioglitazone with various formulations of Metformin hydrochloride (SR) tablet. The release profile of Pioglitazone was studied in dissolution media such as pH 6.8 media showed better release [13-15].

This Bilayered technique is nowadays becoming very popular. This bilayered tablets are initially compressed individually by above mentioned methods and finally they are compressed slowly in the Tablet compression Machine. These Bilayered tablets are differentiated by using a color. For the immediate release tablets, Pioglitazone was mixed with saffron red and they were compressed.

Bilayered tablets using Xanthan gum showed better results when compared to all other gums as it showed prolonged release for 12 hours [16].

Bilayered Tablets of Pioglitazone and Metformin sustained release tablets along with natural gums are used to treat Type 2 Diabetes [17,18] when compared to other conventional tablets.

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